SECTION 5
510(k) SUMMARY

510(k) SUMMARY

AUG 17 2012

1. Submitter:

Boston Scientific Corporation
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Contact: Laurie Pannella
Regulatory Affairs Specialist
Date Prepared: July 20, 2012

2. Proposed Device:

Trade Name: TRUEtome™ Sphincterotome,
Classification Name: Endoscopic Electrosurgical Unit and Accessories
Regulation Number: 876.4300
Product Code: KNS
Classification: Class II

3. Predicate Devices:

Trade Name: Autotome ™ RX Sphincterotome
Manufacturer and Clearance Number: Boston Scientific Corporation, K013153
Classification Name: Endoscopic Electrosurgical Unit and Accessories
Regulation Number: 876.4300
Product Code: KNS
Classification: Class II

Trade Name: Ultratome™ XL Sphincterotome
Manufacturer and Clearance Number: Boston Scientific Corporation, K930022
Classification Name: Endoscopic Electrosurgical Unit and Accessories
Regulation Number: 876.4300
Product Code: FDI
Classification: Class II

4. Proposed Device Description:

TRUEtome™ Sphincterotome when connected to a monopolar current may be used to incise the Papilla of Vater and/or the Sphincter of Oddi. The TRUEtome™ Sphincterotome is a 200 cm, triple lumen sphincterotome that tapers from 7 Fr (2.3 mm) to 5.5 Fr (1.8 mm) with an atraumatic tip. The catheter is capable of accepting a 0.035 in (0.89 mm) Boston Scientific Guidewire and a 0.025 in (0.64 mm) Boston Scientific Guidewire, while injecting and/or cutting using other lumens. The sphincterotome may be placed with or without the aid of a guidewire. When connected to a monopolar current, the sphincterotome may be used to incise the Papilla of Vater and/or the Sphincter of Oddi. The sphincterotome is designed for use with endoscopes that have a working channel of 2.8 mm and larger.

5. Indication for Use:
The Intended Use of the proposed TRUEtome™ Sphincterotome is identical the predicate devices, Autotome ™ RX Sphincterotome and Ultratome™ XL. These devices are indicated for use in the transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The Sphincterotome can also be used cannulate and to inject contrast medium.

6. Technological Characteristics:
The proposed TRUEtome™ Sphincterotomes are similar in design, materials, and manufacturing processes to the predicate, Autotome ™ RX Sphincterotome (K013153) and Ultratome™ XL Sphincterotome (K930022).

7. Performance Data:
Biocompatibility of the proposed device was confirmed via AAMI/ANSI/ISO 10993-1: 2009, and included Cytotoxicity, Intracutaneous Reactivitity (Irritation), Sensitization and USP Physiochemical tests.

EO residual testing was done per AAMI/ANSI/ISO 10993-7: 2008

In-vitro testing has been performed and all components, subassemblies, and/or full devices met the required specifications. The testing included Initial Tip Orientation, Tip Bowing, Tip Bow Holding, Tip Rotation, Guidewire Passage/Compatibility, System Leakage, Tip OD, Luer to Extrusion Integrity. Electrical safety of the device has also been confirmed via IEC 60601-1:1988 A1:1991 A2:1995.

8. Conclusion:
Boston Scientific Corporation has demonstrated that the minor device modifications to the existing predicate Autotome ™ RX Sphincterotome (K013153) are substantially equivalent to the proposed TRUEtome™ Sphincterotome. Therefore, the proposed TRUEtome™ Sphincterotome device is as safe, as effective and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Laurie Pannella
Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752

AUG 17 2012

Re: K122203
Trade/Device Name: TRUEtome™ Sphincterotome
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS
Dated: July 24, 2012
Received: July 25, 2012

Dear Ms. Pannella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K122203

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):	To Be Determined
Device Name:	TRUEtome™ Sphincterotome
Indications For Use:	The TRUEtome™ Sphincterotome devices are indicated for use in transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The sphincterotome can also be used to cannulate and inject contrast medium.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122203